510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE

A. 510(k) Number:

k061818

B. Purpose for Submission:

New device

C. Measurand:

Alkaline Phosphatase

D. Type of Test:

Calibrator material

E. Applicant:

Dade Behring Inc.

F. Proprietary and Established Names:

Dimension Vista™ System Alkaline Phosphatase Calibrator (ALP CAL – KC330)

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
Calibrator, secondary (JIT)	Class II	21 CFR 862.1150 Calibrator	75 Clinical Chemistry (CH)

H. Intended Use:

1. Intended use(s):

   The ALP CAL is an *in vitro* diagnostic product for the calibration of the Alkaline Phosphatase method on the Dimension Vista™ System.

2. Indication(s) for use:

   See Intended use above

3. Special conditions for use statement(s):

   Prescription use only

4. Special instrument requirements:

   Dimension Vista

I. Device Description:

The ALP CAL is a liquid bovine protein product containing alkaline phosphatase from porcine kidney. The kit consists of three vials of Calibrator A. The volume per vial is 1.0 mL. ALP CAL is ready for use, no preparation is required. System water is used as the ALP zero calibrator (Level 1) for the Dimension Vista™ System.

J. Substantial Equivalence Information:

1. Predicate device name(s):

   Dimension® Enzyme Verifier (DC19) and VITROS Chemistry Products Calibrator Kit 3.

2. Predicate K number(s):

   k860021 for Dimension® clinical chemistry system.

3. Comparison with predicate:

Item	Dimension Vista™ System ALP Calibrator (New device)	Dimension® Enzyme Verifier (Predicate device)
Intended Use	The ALP Calibrator is an *in vitro* diagnostic product for the calibration of alkaline phosphatase (ALP) on the Dimension Vista™ System.	Enzyme Verifier is an *in vitro* diagnostic product to be used to verify **alkaline phosphatase (ALP)**, amylase (AMY), g-glutamyl transferase (GGT), aspartame aminotransferase (AST), alanine aminotransferase (ALT) and lactic dehydrogenase (LDH) method performance on the Dimension® clinical chemistry system.
Analytes	Alkaline phosphatase (ALP).	**Alkaline phosphatase (ALP),** Amylase (AMY) g-glutamyl transferase (GGT), Aspartame aminotransferase (AST), Alanine aminotransferase (ALT), Lactic dehydrogenase (LDH).
Form	Liquid.	Lyophilized
Traceability	Master Pool, Dimension® clinical chemistry system values.	Master Pool, Dimension® clinical chemistry system values.
Matrix	Bovine protein, porcine kidney based product.	Human serum, bovine kidney based product.
Calibration / Verification Levels	One level.	Three levels.

K. Standard/Guidance Document Referenced (if applicable):

STANDARDS
Title and Reference Number
Stability Testing of In Vitro Diagnostic Reagents (13640)
Medical devices - Application of risk management to medical devices (14971:2000)

Other Standards

GUIDANCE			
Document Title	**Office**	**Division**	**Web Page**
Guidance for Industry - Abbreviated 510(k) Submissions for In Vitro Diagnostic Calibrators; Final	**OIVD**		**http://www.fda.gov/cdrh/ode/calibrator.html**
Guidance for Industry and FDA Staff - Use of Symbols on Labels and in Labeling of In Vitro Diagnostic Devices Intended for Professional Use			**http://www.fda.gov/cdrh/ocd/guidance/4444.html**

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

   a. *Precision/Reproducibility:*

      Not Applicable

   b. *Linearity/assay reportable range:*

      Not Applicable

   c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*

      Traceability:
      The assigned values of the Alkaline Phosphatase Calibrator are traceable to Master Pool, Dimension® Clinical Chemistry System.

Stability:
Target shelf life for the ALP calibrator is 12 months. Calibrator shelf life (long term) stability is determined by comparing results of the product stored at -70°C with control stored at -20°C. Percent change should be less than or equal to 6%. Shelf-life stability (expiration) dating assignment at commercialization reflects the real-time data on file at Dade Behring, Inc. Open vial (in use) stability is 7 days if kept on the instrument and 30 days if stored in the refrigerator.

Value Assignment:
The new calibrator Master Pool is made by gravimetrically adding quantities of alkaline phosphatase to StabilZyme® AP to target concentrations. Three levels of Master Pool are prepared and stored at -70° C. The concentrations are verified using a previously approved Master Pool lot as a control. The final bottle value for the Master Pool is assigned for each level by testing N = 45 replicates on multiple instruments. A stock solution is prepared for the new commercial calibrator lot by gravimetrically adding alkaline phosphatase to StabilZyme® AP to target concentration. The stock solution concentration is verified by comparing the Master Pool assigned bottle values. For the commercial calibrator lot, calculated quantity of the stock solution is added to StabilZyme® AP to target concentrations. The concentration of the commercial lot is verified to be within acceptable range by using an instrument calibrated with Master Pools. The final bottle value is assigned to the commercial lot level and verified using a previously released commercial lot of calibrator on multiple instruments for N = 45 total replicates.

d. Detection limit:

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

Not applicable

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.